

A35967 – 073226.0119 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

Lee et al.

Serial No.

10/653,350

Examiner

Not Yet Assigned

Filed

September 2, 2003

Group Art Unit:

Not Yet Assigned

For

GLYCOSYLATED HUMAN INTERFERON ALPHA

Customer No.:

21003

INFORMATION DISCLOSURE STATEMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

August 23, 2004

Date of Deposit

Carmella L. Stephens

__

Attorney Name

Patent Reg. No.

Marmula O. BUJYAN

Signature

Data of Cignoture

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§1.97 and 1.98, applicants respectfully request that the documents listed below in reverse chronological order and on the accompanying PTO 1449 be considered

by the Examiner and made of record in the above-referenced application. Copies of the documents listed are enclosed.

- United States Patent No. 6,399,103 by Yamagata et al., entitled "Method of Producing a Sustained Release Preparation," issued June 4, 2002.
- International Patent Application Publication No. WO 98/48840, entitled "Polyethylene
 Glycol-Interferon Alpha Conjugates for Therapy of Infection," published November 5, 1998.
- 3. Radhakrishnan et al., (1996)"Zinc mediated dimer of human interferon-α_{2b} revealed by X-ray crystallography", Structure vol.4, 1453-1463.
- Adolf et al., (1991) "Natural human interferon-α2 is O-glycosylated", Biochem. J., 276 (Pt
 2), 511-518.
- 5. United States Patent No. 4,931,373 by Kawasaki et al., entitled "Stable DNA Constructs for Expression of α-1 Antitrypsin," issued June 5, 1990.
- Sambrook, J. Fritsch, E.F., Maniatis, T., (1989) Molecular Cloning A Laboratory Manual,
 2nd Edition, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York. (Table of Contents)
- 7. DeMaeyer and DeMaeyer-Guignard, (1988) Interferons and other regulatory cytokines, Wiley, New York. (Table of Contents)
- 8. Tovey et al. (1987) "Interferon messenger RNA is produced constitutively in the organs of normal individuals", Proc Natl Acad Sci USA, vol. 84, 5038-5042.
- 9. Pestka et al. (1982) "Interferons and their actions", Annu. Rev. Biochem., 56, 727-777.
- 10. Davis et al. (1986) Basic Methods in Molecular Biology, Elsevier Science Publishing Co.
- 11. Lengyel P. (1982) "Biochemistry of interferons and their actions", Annu. Rev. Biochem., 51,

NY02:472024.1 2

251-282.

- 12. Branca and Baglioni (1981) "Evidence that types I and II interferons have different receptors", Nature 294, 768-770.
- 13. Isaacs and Lindenmann (1957) "Virus interference. I. The interferon", National Institute for Medical Research, London, 258-267.

Identification of the listed documents is not to be construed as an admission of the applicants or attorneys for applicants that such citations are available as "prior art" against the subject application. If the Examiner applies the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

NY02:472024.1 3

There should be no fee required for this submission. However, if any fee is required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this paper is enclosed.

Respectfully submitted, BAKER BOTTS L.L.P.

Carmella L. Stephens PTO Reg. No. 41,328

30 Rockefeller Plaza 44th Floor New York, NY 10012-4498

Attorneys for Applicants (212) 408 2500

There should be no fee required for this submission. However, if any fee is required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this paper is enclosed.

Respectfully submitted, BAKER BOTTS L.L.P.

Carmella L. Stephens PTO Reg. No. 41,328

30 Rockefeller Plaza 44th Floor New York, NY 10012-4498

Attorneys for Applicants (212) 408 2500

4

Form PTO (REV. 2-82			Depar					•	Atty. Dočket No. A35967 – 073226.0119		Serial No. 10/653,350			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (See several sheets if necessary)									Applicants Lee et al.					
									Filing Date September 2, 2003	I	Group Art Unit Not Yet Assigned			
AUB 2 5	2004	-	-											
									T DOCUMENTS					
TA TRAI	EUR	Document No.						Date	Name	Class	Subclass	Filing Date ifAppropriate		
	6	3	9	9	1	0	.3	06/04/02	Yamagata et al.	424	489			
4	4	9	3	1	3	7	3	06/05/90	Kawasaki et al.	435	69.2			
,								FOREIGN PA	TENT DOCUMENT					
÷.		Document No.								Class	SubClass	Trans Yes	<u>lator</u> No	
	9	8	4	8	8	4	0	11/05/98	WO	Class	Subclass	163	140	
				отн	ER D	OCU	MEN	TS (including	Author, Title Date, Pertinent P	ages, Etc.)		<u> </u>	1	
		Radhakrishnan et al., (1996)"Zinc mediated dimer of human interferon-α _{2b} revealed by X-ray crystallography", Structure vol.4, 1453-1463.												
·		Adolf et al., (1991) "Natural human interferon-α2 is O-glycosylated", Biochem. J., 276 (Pt 2), 511-518.												
		1							., (1989) Molecular Cloning y Press, Cold Spring Harbo	-	•	nual, 2nd	i	
		DeMaeyer and DeMaeyer-Guignard, (1988) Interferons and other regulatory cytokines, Wiley, New York.												
:		Tovey et al. (1987) "Interferon messenger RNA is produced constitutively in the organs of normal individuals", Proc Natl Acad Sci USA, vol. 84, 5038-5042.												
		Pestka et al. (1982) "Interferons and their actions", Annu. Rev. Biochem., 56, 727-777.												
		Davis et al. (1986) Basic Methods in Molecular Biology, Elsevier Science Publishing Co.												
			ngye 1-282		(198	2) "F	Bioch	nemistry of i	nterferons and their actions	s", Annu.	Rev. Bio	ochem.,	51,	
			anca ture 2				(198	1) "Evidence	that types I and II interfer	ons have	different	receptor	s",	
								(1957) "Viru n, 258-267.	s interference. I. The inter	feron", N	National I	nstitute	for	

Date Considered

Examiner

^{*} Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.